IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC., **Plaintiff,** **v.** **RICONPHARMA LLC and INGENUS PHARMACEUTICALS, LLC,** **Defendants.**	Civ. No. 21-12133 (KM) (MAH) **OPINION**

KEVIN MCNULTY, U.S.D.J.:

This patent infringement case is brought by Supernus Pharmaceuticals, Inc. ("Supernus") against RiconPharma LLC and Ingenus Pharmaceuticals, LLC (collectively, "Ricon"). The patents-in-suit are Patent Nos. 7,722,898 ("the '898 patent"), 7,910,131 ("the '131 patent"), 8,617,600 ("the '600 patent"), 8,821,930 ("the '930 patent"), 9,119,791 ("the '791 patent"), 9,351,975 ("the '975 patent"), 9,370,525 ("the '525 patent"), 9,855,278 ("the '278 patent"), and 10,220,042 ("the '042 patent"). These patents describe a formulation for an extended-release oxcarbazepine tablet used to treat epilepsy.

Supernus commenced this infringement action after Ricon sought approval for a generic extended-release oxcarbazepine tablet. This Opinion contains the Court's construction of key patent terms following a *Markman* hearing.[1]

[1] The reference is to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996).

I. Background

Oxcarbazepine is an antiepileptic drug used for the treatment of partial seizures in adults and children. ('898 Patent 1:20–25.)[2] It was first approved in the United States in 2000 in the form of a tablet for twice-a-day administration. (Supernus PPT 8.)

The invention claimed by the patents-in-suit consists of a controlled-release formulation of oxcarbazepine that is administered only once daily, yet still meets the therapeutic needs of patients. ('898 Patent 2:20–25.) Patient compliance generally improves with dosage forms that require only once-a-day administration, and there are significant clinical advantages, including better therapeutic efficacy and reduced side effects, that accompany such dosage forms. (*Id.* at 1:20–35.) Supernus's Oxtellar XR, which is an embodiment of the patents-in-suit, is the first and only oxcarbazepine formulation for once-a-day administration that is on the market. (Supernus Br. 3.)

It is difficult to create a controlled-release formulation of oxcarbazepine because the drug is poorly soluble in water. ('898 Patent 1:41-53; Supernus Br. 3.) Poor solubility causes the release of oxcarbazepine from sustained release dosage forms to be incomplete, leading to reduced bioavailability of the drug and therapeutic ineffectiveness. (*Id.*) The invention covered by the patents-in-suit incorporates "a combination of solubility-enhancing excipients and/or release-promoting agents into the formulations to enhance the bioavailability of

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[2] Certain key items from the record will be abbreviated as follows:
DE = Docket entry number in this case
Compl. = Supernus's complaint for patent infringement (DE 1)
'898 Patent = Patent No. 7,722,898 (DE 80-2)
Supernus PPT = Supernus's PowerPoint presentation from *Markman* hearing
Supernus Br. = Supernus's opening claim construction brief (DE 80)
Supernus Resp. Br. = Supernus's responsive claim construction brief (DE 87)
Ricon Br. = Ricon's opening claim construction brief (DE 78)
Ricon Resp. Br. = Ricon's responsive claim construction brief (DE 85)

oxcarbazepine and its derivatives." ('898 Patent 3:57-60.) Together, these components create a "controlled-release" composition that releases the drug at varying rates over time. (*Id.* at 5:30-65.) The invention also incorporates "matrix" polymers that serve as carriers for the oxcarbazepine, solubility enhancers, and release promoters. (*Id.* at 5:52-59.) The invention thus has four key components: (1) oxcarbazepine, (2) a matrix-forming polymer, (3) a solubility enhancer, and (4) a release-promoting agent. (Supernus Br. 3.)

According to the complaint, filed on June 3, 2021, Ricon submitted to the FDA an Abbreviated New Drug Application ("ANDA") No. 21579, seeking approval to engage in the commercial manufacture and sale of generic oxcarbazepine extended-release tablets. (Compl. ¶10.) Supernus alleges that the Ricon product infringes the patents-in-suit and seeks appropriate relief.

The Court held a *Markman* hearing on October 19, 2022. (DE 100.) Prior to the hearing, the parties submitted opening briefs, as well as briefs in response. (DE 78, 79, 80, 85, 87.) I am now prepared to rule on the meaning of the disputed claim terms.

II. Legal standards

A patent infringement case involves two steps. First, the court determines the meaning of the claims in the patent. *Amgen Inc. v. Amneal Pharms. LLC*, 945 F.3d 1368, 1375 (Fed. Cir. 2020). Second, the court compares the claims, as construed, to the allegedly infringing product. *Id.*

We are now concerned with the first step, known as claim construction. Where, as here, the parties dispute the meaning of the patent's claims, resolution of those disputes is an issue for the court. *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 977 (Fed. Cir. 2021). This task primarily requires construal of written documents (quintessentially, the patent itself), but some factual determinations may be needed to assist in understanding the written words. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325–26 (2015). Accordingly, there is a hierarchy of sources to be considered when construing a

claim, arranged in decreasing order of importance. *Profectus Tech. LLC v. Huawei Techs. Co.*, 823 F.3d 1375, 1380-81 (Fed. Cir. 2016).

Of course, I "begin with the words of the claims themselves." *Allergan Sales, LLC v. Sandoz, Inc.*, 935 F.3d 1370, 1373 (Fed. Cir. 2019) (citation omitted). Those words receive the meaning that "a person of ordinary skill in the art" ("POSA") would give them. *Id.* (citation omitted). A POSA would interpret the words in the context of the rest of the patent document, including the specification which describes the invention. *Id.* at 1373 & n.6. The prosecution history, *i.e.*, proceedings before the U.S. Patent and Trademark Office that led to approval of the patent, can further illuminate the meaning of a term. *Id.* at 1373 & n.7. All of the foregoing constitutes "intrinsic evidence," *i.e.*, evidence from within the patent process itself.

I may also turn to "extrinsic evidence," or evidence outside the patent and prosecution history. *Id.* at 1373 & n.8. Such extrinsic evidence includes "expert and inventor testimony, dictionaries, and learned treatises." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (en banc). In general, however, extrinsic evidence is less reliable than the patent and prosecution history. *Id.* at 1318. For that reason, extrinsic evidence is second-priority, and cannot "trump the persuasive intrinsic evidence." *Immunex Corp. v. Sanofi-Aventis U.S. LLC*, 977 F.3d 1212, 1221–22 (Fed. Cir. 2020) (citation omitted).

The parties have appropriately drawn the Court's attention to several cases that have previously been litigated in this district concerning the patents-in-suit. These cases are *Supernus Pharmaceuticals, Inc. v. Activis, Inc. et al.*, Nos. 13-cv-4740 and 14-cv-1981 ("*Activis*"), *Supernus Pharmaceuticals, Inc. v. TWi Pharmaceuticals, Inc. et al.*, Nos. 15-cv-369 and 17-cv-2164 ("*TWi*"), and *Supernus Pharmaceuticals, Inc. v. Apotex et al.*, No. 20-cv-7870 ("*Apotex*"). Certain of the claim terms at issue here have been construed by the judges presiding over those cases. I consider those prior rulings, but bear in mind that, as extrinsic evidence, they cannot override this Court's obligation to consider for itself, and give priority to, the patent language and prosecution

history. *See American Innotek, Inc. v. United States*, 126 Fed. Cl. 468, 484 (2016) (construction of the same term by other courts constitutes extrinsic evidence).

III. Discussion

The parties have identified two claim terms that require construction by the Court. These terms are both found in claim 1 of each of the patents-in-suit. Claim 1, abridged to highlight the language relevant to the terms to be construed here, reads as follows:

> "A pharmaceutical formulation for once-a-day administration of oxcarbazepine comprising a homogeneous matrix comprising:
> (a) oxcarbazepine
> (b) a matrix-forming polymer . . .
> (c) at least one agent that enhances the solubility of oxcarbazepine . . . and;
> (d) at least one release-promoting agent comprising a polymer having pH-dependent solubility selected from the group consisting of . . . ."

A. Homogeneous matrix term

Term	Supernus's Construction	Ricon's Construction
"A pharmaceutical formulation comprising . . . a homogeneous matrix comprising"	A pharmaceutical formulation . . . comprising a matrix in which the ingredients or constituents are uniformly dispersed comprising	A pharmaceutical formulation in which the ingredients are uniformly dispersed throughout the entire dosage form and has a structure that maintains its shape during drug release and serves as a carrier for the ingredients

The first disputed claim term is "[a] pharmaceutical formulation . . . comprising a homogenous matrix comprising . . . ." I refer to this as the "homogeneous matrix term".

The parties apparently agree that the term "pharmaceutical formulation" requires no construction. They also agree that the word "homogeneous" means that the ingredients listed in subparts (a), (b), (c), and (d) of claim 1 ("ingredients (a), (b), (c), and (d)", as I refer to them) must be uniformly

dispersed. (Supernus Br. 1; Ricon Br. 15.) The core of the dispute is whether those ingredients must be uniformly dispersed in a matrix (Supernus's position), or whether they must be uniformly dispersed throughout the entire tablet or dosage form (Ricon's position). (Supernus Response Br. 4.) Under Ricon's proposed construction, the patents-in-suit would exclude multi-layer tablets having different ingredients or different proportions of ingredients in different layers of the tablet. Under Supernus's proposed construction, multi-layer tablets would be covered by the patents-in-suit, so long as there is a matrix inside at least one layer of the tablet in which ingredients (a), (b), (c), and (d) are uniformly dispersed.

Supernus's proposed construction is more directly aligned with the claim language. "'Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997) (citation omitted). "[T]he transitional term 'comprising' . . . is open-ended and does not exclude additional, unrecited elements or method steps." *Mars, Inc. v. H.J. Heinz Co., L.P.*, 377 F.3d 1369, 1376 (Fed. Cir. 2004) (internal quotation marks omitted).[3] I agree with

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[3] As noted in *Genentech,* "comprising" is a term of art in patent law. Here is a non-technical dictionary definition:

> com·prise | \ kəm-ˈprīz \
> comprised; comprising
> Definition of comprise
>
> *transitive verb*
> 1: to be made up of
> The factory was to be a vast installation, comprising fifty buildings.
> — Jane Jacobs
> The play comprises three acts.
>
> 2: COMPOSE, CONSTITUTE
> … a misconception as to what comprises a literary generation.
> — William Styron
> … about 8 percent of our military forces are comprised of women.
> — Jimmy Carter

Supernus that, based on the claim language alone, the patents-in-suit appear to cover formulations that have a homogeneous matrix, even if they *also* have other unrecited layers, components, or structures. On the other hand, Ricon's proposed construction is at odds with the claim language in that it effectively reads out the word "comprising," as understood in patent law, from the claim. *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 951 (Fed. Cir. 2006) (it is a principle of claim construction that "claim language should not [be] treated as meaningless").

The patent specification lends support to Supernus's proposed construction as well. The specification states that "[t]his invention also pertains to multi-layer tablets. Multi-layer tablets can be prepared with each layer releasing the drug at a rate that is different from the rate of release from another layer. In multi-layer tablets, each layer may or may not be coated." ('898 Patent 2:45–50.)

Arguably, the type of multi-layer tablet described in these sentences could be one in which (1) each of the layers contains a homogeneous matrix with ingredients (a), (b), (c), and (d), as opposed to (2) the layers have differing ingredients or proportions of ingredients. Importantly, however, the language of the patent would appear to cover both types, and nowhere in the specification is there any disclaimer of multi-layer tablets of the latter type, so long as the homogeneous matrix is present. Apart from the few sentences quoted above, the specification does not define the overall tablet structure.

> 3: to include especially within a particular scope
> … civilization as Lenin used the term would then certainly have comprised the changes that are now associated in our minds with "developed" rather than "developing" states.
> — The Times Literary Supplement (London)

"Comprise." Merriam-Webster.com Dictionary, Merriam-Webster, https://www.merriam-webster.com/dictionary/comprise. Accessed 27 Oct. 2022. As used here, "comprising" perhaps corresponds most closely to definition 3, rather than the more common definition 1. (Merriam-Webster notes that definition 2 has been criticized as substandard.)

As a general rule, "the claims of [a] patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004), quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002). "Absent a clear disclaimer of particular subject matter, the fact that the inventor may have anticipated that the invention would be used in a particular way does not mean that the scope of the patent is limited to that context." *Northrop Grumman Corp. v. Intel Corp.*, 325 F.3d 1346, 1355 (Fed. Cir. 2003). *See Liebel-Flarsheim*, *supra* at 907, 912 (where specification for patented fluid injector contained no disclaimer of embodiments that lack pressure jackets, court concluded that the claims did not require pressure jackets, even though all discussed embodiments had pressure jackets).

Supernus may well have anticipated that its invention would take the form of a single-layer tablet or a multi-layer tablet with a homogeneous matrix in each of the layers. Still, there is no basis in the patent itself for such a limitation. The specification gives no indication that the overall tablet structure matters for the formulation to function effectively; all that is apparently required for effective functioning is that there be—somewhere inside the tablet— a homogeneous matrix that contains ingredients (a), (b), (c) and (d).

Ricon resorts to extrinsic evidence to support its proposed construction of the homogeneous matrix term. It points primarily to the following statements made by Supernus's expert in the *Activis* litigation, Dr. Steven R. Little, in a declaration he submitted to the court:

> [T]he term 'homogeneous' was added to distinguish Supernus's formulations from prior-art formulations that had certain matrix components contained solely in a coating separate from the tablet core or, likewise, formulations with intentional compartmentalization, such as a bilayer tablet. (DE 78-3 ¶31.)
>
> In a bilayer tablet, the manufacturing process is intentionally designed to produce a product that is not homogeneous. (*Id.* at ¶106.)

> I have repeatedly made clear that dosage forms such as bilayer tablet formulations are not homogeneous matrices as claimed by the patents in suit.

(*Id.* at ¶41.) According to Ricon, these statements demonstrate that a bilayer tablet does not constitute a "homogeneous matrix." (Ricon Br. 17.)

Supernus responds that those statements are taken out of context; a particular bilayer tablet may or may not comprise a homogeneous matrix, but the mere fact of its being a bilayer tablet is not determinative. Dr. Little never stated that the "homogeneous matrix" must extend throughout the entire dosage form. (Supernus Resp. Br. 7.) Rather, according to Supernus, when Dr. Little referred to bilayer tablets, he meant tablets in which one or more of ingredients (a), (b), (c), and (d) was *solely* present in a separate layer; for example, a bilayer tablet in which ingredient (a) was only in the top layer, while ingredients (b), (c), and (d) were uniformly dispersed in the bottom layer. (*Id.* at 8-10.) Supernus notes in particular that the statement quoted in the preceding paragraph was followed by this clarification by Dr. Little:

> To be clear, my position is that if the matrix components—1(a) – 1(d)—are sufficiently mixed according to known methods and standards, the result will be a homogeneous matrix as claimed in the patents in suit where the excipients are uniformly dispersed throughout the matrix.

(DE 78-3 ¶41.)

Supernus's characterization of Dr. Little's statements is plausible. Conversely, Ricon's characterization of the statements is far from compelling.

The same goes for Ricon's characterization of a statement by Judge Bumb, who presided over the *Activis* case, in her final opinion on the merits. In *Activis*, the defendants sought to argue, *inter alia*, that Supernus's patents were invalid on the grounds that they were obvious in light of the prior art. *Supernus Pharmaceuticals, Inc. v. Activis, Inc. et al.,* No. 13-4740, 2016 WL 527838, at *30 (D.N.J. Feb. 5, 2016). One such prior art reference, the Rudnic patent (U.S. Patent No. 5,325,570) had three different units in each tablet.

Judge Bumb distinguished Supernus's patents from the Rudnic patent on the following basis:

> The formulations in the Rudnic Patent require three different units in order for them to work. Rather than having all the constituents uniformly dispersed across a matrix tablet, the formulations disclosed in the Rudnic Patents include separate pellets in each dose. Multi-pellet formulations are not homogeneous matrix formulations.

(*Id.* at *33 (cleaned up)). Ricon argues, based on this statement, that the patents-in-suit do not encompass multi-layer tablets.

Supernus's response is analogous to its response to Dr. Little's statements. Judge Bumb's conclusion, says Supernus, that "multi-pellet formulations are not homogeneous matrix formulations" applied to the facts and issues before her; it was not intended as a ruling that a multi-pellet formulation, by virtue of that fact, *cannot* comprise a "homogeneous matrix formulation comprising." Judge Bumb merely concluded that a tablet in which the essential components are localized in different units, rather than uniformly dispersed in a matrix, is not a homogeneous matrix formulation. Read onto this case, the issue would be whether a "multi-pellet formulation" wherein one unit contains a matrix in which all essential components are uniformly dispersed may constitute "a pharmaceutical formulation . . . comprising a homogeneous matrix comprising." Supernus is correct that Judge Bumb never said it could not.

There is no indisputably correct interpretation to be drawn from these isolated pieces of evidence, which are not precisely on point. Particularly under such circumstances, the Court must be sensitive to the lesser status of extrinsic evidence, and wary of allowing it to outweigh intrinsic evidence. *See Phillips*, 415 F.3d at 1318 (noting potential for bias in evidence prepared for litigation, as opposed to evidence arising from the patent process itself). Given that a different set of issues was at play in the *Activis* litigation, I cannot say with certainty what Dr. Little and Judge Bumb meant when they used the terms "bilayer" and "multi-layer" tablets. And the happenstance that a tablet is

bilayer/multi-pellet, or not, does not appear to map very well onto the disputed term here; indeed, it appears that a bilayer/multi-pellet tablet might be engineered to comply with either side's construction of this disputed term.

At bottom, the extrinsic evidence offered by Ricon is not sufficiently clear to displace the plain language of the claim and the absence of any disclaimer in the specification. *See id.* at 1324 (extrinsic evidence may not be used "to contradict claim meaning that is unambiguous in light of the intrinsic evidence"). I therefore conclude that, with respect to the core dispute of the homogeneous matrix term, the matrix constituents need not be uniformly dispersed throughout the entire dosage form.[4]

I turn to the second portion of Ricon's proposed construction of the homogeneous matrix term: that it must have "a structure that maintains its shape during drug release and serves as a carrier for the ingredients." As support, Ricon points to the specification, which states as follows:

> The desired drug release pattern contemplated by this invention is achieved by using 'matrix' polymers that hydrate and swell in aqueous media, such as biological fluids. As these polymers swell, they form a homogeneous matrix structure that maintains its shape during drug release and serves as a carrier for the drug, solubility enhancers and/or release promoters.

('898 Patent, 5:53-59.; Ricon Br. 16.)

Ricon quotes this language from the specification, and notes that Judge Bumb relied on it in the *TWi* litigation to find that there was an adequate written description for the words "homogeneous matrix." Ricon offers no explanation, however, as to why this additional language should be considered

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[4] Ricon also makes a judicial estoppel argument, which I reject for the same reason that I do not find Judge Bumb's and Dr. Little's statements in *Activis* to be persuasive evidence of the meaning of the homogeneous matrix term. "[J]udicial estoppel is an extreme remedy, to be used only 'when the inconsistent positions are tantamount to a knowing misrepresentation to or even fraud on the court.'" *Chao v. Roy's Const., Inc.*, 517 F.3d 180, 186 n.5 (3d Cir. 2008), quoting *Krystal Cadillac-Oldsmobile GMC Truck, Inc v. Gen. Motors Corp.*, 337 F.3d 314, 324 (3d Cir. 2003). Ricon has failed to identify any statements by Supernus that are unambiguously inconsistent with the position Supernus takes here.

a necessary part of the definition of a "homogeneous matrix comprising." Supernus, for its part, maintains that the quoted excerpt performs another function entirely: it merely describes certain matrix polymers before, during, and after the dosage form is administered to a patient. (Supernus Br. 9.)

In both *Activis* and *TWi*, Judge Bumb construed the term "homogeneous matrix" as "a matrix in which the ingredients or constituents are uniformly dispersed." *Supernus Pharmaceuticals, Inc. v. TWi Pharmaceuticals, Inc.*, 265 F. Supp. 3d 490, 498 (2017). That claim language sets forth, in part, the metes and bounds of the claim. True, in *TWi* (a case well past the claim construction phase), Judge Bumb cited this additional written description, but she did not include it as part of her *construction* of the term "homogeneous matrix." And Supernus's proposed construction of "a pharmaceutical formulation . . . comprising a homogeneous matrix comprising," a more complex term, is entirely consistent with Judge Bumb's construction of "homogeneous matrix."

Seeing no good reason to depart from the claim language, and good reason to construe the homogeneous matrix term in a manner consistent with the decision of Judge Bumb, I reject Ricon's redeployment of the written description, "a structure that maintains its shape during drug release and serves as a carrier for the ingredients," to limit the scope of the claims. *See Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1347 (Fed. Cir. 1998) ("[I]t is the *claims*, not the written description, which define the scope of the patent right.")

I therefore adopt Supernus's proposed construction of the homogeneous matrix term as "a pharmaceutical formulation . . . comprising a matrix in which the ingredients or constituents are uniformly dispersed comprising . . . ."

B. pH-dependent polymer term

Term	Supernus's Construction	Ricon's Construction
"release promoting agent comprising a polymer having pH-dependent solubility selected from the group consisting of [10 recited species of polymers]"	An agent that functions to enhance the release rate of the oxcarbazepine comprising a polymer having pH-dependent solubility selected from the group consisting of [10 recited species of polymers]	A release promoting agent comprising a polymer selected from the group consisting of [10 recited species of polymers] which remains insoluble until it reaches a particular pH value higher than 4.0, at which point it dissolves, enhancing the release rate of the oxcarbazepine

The second disputed claim term is "release promoting agent comprising a polymer having pH-dependent solubility selected from the group consisting of [10 recited species of polymers]." I will refer to this as the "pH-dependent polymer term".

The parties' central dispute with respect to the pH-dependent polymer term involves the meaning of the phrase "polymer having pH-dependent solubility." (Supernus Br. 11; Ricon Br. 10.) Supernus asserts that the meaning is plain on its face to a POSA and requires no construction, while Ricon contends that the specification defines a pH-dependent polymer, in the context of the patents-in-suit, as one that is insoluble at pH values below 4.0 and soluble at pH values above 4.0. (Supernus Br. 11; Ricon Br. 10-11.)

At the heart of this dispute is the question of whether Ricon is impermissibly reading a limitation from a patent specification into a claim. The Federal Circuit, analyzing this oft-presented question, has "recognized that 'there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification.'" *Liebel-Flarsheim,* 358 F.3d at 904–05, quoting *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186–87 (Fed. Cir. 1998). The Federal Circuit has

"explained that 'an inherent tension exists as to whether a statement is a clear lexicographic definition or a description of a preferred embodiment. The problem is to interpret claims in view of the specification without unnecessarily importing limitations from the specification into the claims.*" Id.*, quoting *E–Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369 (Fed. Cir. 2003). Without imposing any independent limitation, the words of the specification may nevertheless provide context that illuminates the meaning of the claims.

With this perspective in mind, I turn to the relevant excerpts from the specification. The specification states as follows:

> A combination of solubility and release promoters is contemplated in this invention. Preferable release promoting agents are pH-dependent polymers, *also known as enteric polymers*.[5] These materials are well known to those skilled in the art and *exhibit pH dependent solubility such that they dissolve at pH values higher than about 4.0 while remaining insoluble at pH values lower than 4.0* . . . . When a formulation containing both the enteric polymer and solubilizer is exposed to an aqueous media of pH higher than 4.0, the enteric polymer dissolves rapidly leaving a porous structure, resulting in increased contact surface between the aqueous medium and the poorly soluble drug. This increased surface area enhances the efficiency of the solubilizer(s), and hence, the overall solubility and release rate of the drug is enhanced to a point where it impacts the availability of the drug for systemic absorption in patients.

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[5] For reference, here is the dictionary definition of "enteric":

> enteric adjective
> en·ter·ic | \ en-ˈter-ik , in- \
> Definition of enteric
> 1: of, relating to, or affecting the intestines
> *broadly* : ALIMENTARY
> 2: being or having a coating designed to pass through the stomach unaltered and disintegrate in the intestines
> //enteric aspirin

"Enteric." Merriam-Webster.com Dictionary, Merriam-Webster, https://www.merriam-webster.com/dictionary/enteric. Accessed 27 Oct. 2022. There is no indication in the patent that any specialized or idiosyncratic definition was intended.

('898 Patent at 4:14-31.) (Emphasis added.) Ricon argues that the use of the phrase "such that" in this excerpt demonstrates that pH-dependent solubility, in the context of the patents-in-suit, must mean dissolving at pH values higher than about 4.0 while remaining insoluble at pH levels lower than that. The very essence of this invention, says Ricon, is that "just any sort of change of solubility with change of pH is not sufficient; [rather,] these polymers must be insoluble below a pH of 4.0 and soluble at some suitable pH above 4.0." (Ricon Br. 11-12.) Ricon finds confirmation of that view in the following, separate portion of the specification:

> All enteric polymers that remain intact at pH values lower than about 4.0 and dissolve at pH values higher than 4.0, preferably higher than 5.0, most preferably about 6.0, are considered useful as release-promoting agents for this invention.

(*Id.* at 4:38-42.)

These excerpts, then, appear to equate a pH-dependent polymer with an enteric polymer having a pH inflection point of about 4.0. By themselves, these excerpts are persuasive evidence that Ricon's proposed construction is correct, but they are not quite definitive. They do not literally state whether having a polymer insoluble at pH<4.0 and soluble at some pH> 4.0 is an essential aspect of the invention, or merely a preferred embodiment.

As additional support for its essentialist interpretation, Ricon points to the intrinsic prosecution history of the patents-in-suit, and also cites extrinsic statements made by Dr. Padmanabh P. Bhatt, a named inventor of the patents-in-suit, in related litigation.

During the prosecution of the patents-in-suit, Supernus explained that it is important to have as a component of the formulation a polymer having pH-dependent solubility *because* that polymer will remain insoluble until it reaches the appropriate intestinal region of the gastrointestinal tract. (DE 79-2 at 63.) ("The term 'enteric polymer' is specifically reserved for polymers that are pH-dependent, meaning that they remain *in*soluble until they reach the appropriate region of the GI tract having a pH at which the polymer dissolves.")

For purposes of this patent, then, an equivalence between a "pH-dependent polymer" and an "enteric polymer" is suggested.

Dr. Bhatt elaborated on the functional significance of the pH-dependent polymer in both *Activis* and *TWi.*

At the *Activis* trial, Dr. Bhatt testified that "[a]n enteric polymer is a pH-dependent polymer that does not dissolve particularly in the stomach pH but will dissolve at pHs higher in the intestinal tract." (DE 78-1 at 4, lines 1-3.) In his *Activis* deposition testimony, Dr. Bhatt also explained why the specification identifies polymers that dissolve at a pH level of 5 as being preferable to those that dissolve at a pH level of 4, and polymers that dissolve at a pH level of 6 as being more preferable still: "Because we were trying to utilize the functionality of the enteric polymer to create channels in the lower portions of the GI tracts. So as you go down the GI tract, the pH values, typically, go up towards neutrality." (DE 85-2 at 3.)

At the *TWi* trial, Dr. Bhatt testified that the release promoter was added to the formulation after it became clear that the solubility enhancer was not doing the job on its own. He explained:

> We ended up adding what we are terming a release promoter, and what we chose was a release promoter that was a pH dependent polymer, which will dissolve at a pH higher than the pH of the stomach, and in our case we ended up choosing the particular embodiment of Eudragit L100-55, which is a brand name of a polymer that dissolves at pH 5.5 plus/minus. Right? And the idea was that when you add this polymer in the dosage form, the tablet goes into the GI tract, goes into the intestinal region, the pH changes, this material will dissolve at this time—remember, it is in the tablet, when it dissolves, it leaves behind porous cavities. Right? And those cavities will create channels in the tablet now that will allow aqueous media from the GI tract to come in and allow the solubility enhancers to do their job and help oxcarbazepine dissolve.

(DE 79-3 at 6, lines 5-19.)

Dr. Bhatt's statements, although extrinsic, are highly pertinent to the claim construction analysis insofar as they explain the role of the pH-

dependent polymer in the invention. Those statements make clear that it is not simply preferred to have a polymer that dissolves at pH levels higher than that of the stomach; on the contrary, it is an essential feature of the invention that the pH-dependent polymer remain intact in the stomach and dissolve only upon reaching the intestinal region. At that point, "aqueous media from the GI tract" are absorbed into the tablet, allowing the solubility enhancers to "do their job and help oxcarbazepine dissolve." As Supernus itself admits, addressing oxcarbazepine's poor solubility was a "serious challenge" that it overcame in inventing an effective once-daily oxcarbazepine formulation. (Supernus Br. 3.)

Per Dr. Bhatt's testimony in *TWi*, the embodiment branded as Oxtellar XR utilizes a polymer that dissolves at a pH value of 5.5, but a polymer that dissolves at a pH value of 4.5, or 6, would also do. The polymer need only remain intact until it passes through the stomach,[6] and dissolve once it reaches a pH level sufficiently higher than that. As evidenced by the specification, the dividing line that Supernus chose for its invention is a pH level of about 4.0.

Supernus argues that Ricon's proposed construction of the pH-dependent polymer term violates the doctrine of claim differentiation, which forbids reading into an independent claim a limitation that is explicitly set forth in a separate dependent claim. (Supernus Br. 11.) Dependent claim 17 of the patents-in-suit covers "[t]he pharmaceutical formulation of claim 1, wherein the polymer having pH-dependent solubility remains intact at pH values of below 4 and dissolves at pH levels of more than 4." Supernus maintains that Ricon's proposed construction of the pH-dependent polymer term has the same

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[6] In the stomach, normal pH levels range between 1.5 and 3.5. *See* National Institutes of Health, National Library of Medicine, Medline Plus, *Stomach acid test*, https://medlineplus.gov/ency/article/003883.htm#:~:text=The%20normal%20volume%20of%20the,%2Fhr)%20in%20some%20cases (visited Oct. 27, 2022); *accord* University of California, San Francisco, *Stomach acid test*, https://www.ucsfhealth.org/medical-tests/stomach-acid-test (visited Oct. 27, 2022). It appears that pH levels may vary, however, even as between portions of the stomach.

scope as dependent claim 17 and therefore would render the dependent claim superfluous.

The doctrine of claim differentiation gives rise to a "rebuttable presumption" only. *See Howmedica Osteonics Corp. v. Zimmer, Inc.*, 822 F.3d 1312, 1323 (Fed. Cir. 2016). That presumption may be overcome by a contrary construction dictated by the specification, prosecution history, and any relevant extrinsic evidence. *Id. See Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1480 (Fed. Cir. 1998). In particular, the claim differentiation presumption cannot be employed to "broaden claims beyond their correct scope," which must be determined in light of the sources listed above. *Medzam*, *supra*.

In this instance, the presumption of claim differentiation is overcome. As set forth above, the specifications, an excerpt from the prosecution history, and testimony by named inventor Dr. Bhatt reveal that what was invented consisted of a formulation that utilizes a polymer that dissolves at pH levels higher than about 4.0. While an expansive reading of "pH-dependent polymer" to mean *any* pH is possible, it makes little sense in context; a polymer that dissolves at a pH value of 1.0, for example, is nonsensical in the context of what all agree to be the science underlying this invention. It is noteworthy, also, that dependent claims 18 and 19—the only other dependent claims that specifically discuss the polymer having pH-dependent solubility—cover "[t]he pharmaceutical formulation of claim 1, wherein the polymer having pH-dependent solubility dissolves at pH values" of "more than 5" and "more than 6," respectively. At a minimum, the claims never suggest that the pH-dependent polymer could be anything *other than* an enteric polymer that dissolves at pH levels higher than 4.

I therefore conclude that Ricon's proposed construction of the pH-dependent polymer term is the correct one. I construe the term "release promoting agent comprising a polymer having pH-dependent solubility selected from the group consisting of [10 recited species of polymers]" as a release

promoting agent comprising a polymer selected from the group consisting of [10 recited species of polymers] which remains insoluble until it reaches a particular pH value higher than 4.0, at which point it dissolves, enhancing the release rate of the oxcarbazepine.

IV. Conclusion

I construe the disputed terms as follows:

1. "[a] pharmaceutical formulation . . . comprising a homogenous matrix comprising" means a pharmaceutical formulation . . . comprising a matrix in which the ingredients or constituents are uniformly dispersed comprising
2. "release promoting agent comprising a polymer having pH-dependent solubility selected from the group consisting of [10 recited species of polymers]" means a release promoting agent comprising a polymer selected from the group consisting of [10 recited species of polymers] which remains insoluble until it reaches a particular pH value higher than 4.0, at which point it dissolves, enhancing the release rate of the oxcarbazepine

A separate order will issue.

Dated: October 28, 2022

/s/ Kevin McNulty

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Hon. Kevin McNulty
United States District Judge